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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/717,275	11/18/2003	Ling Yuk Cheung	KONG-29 7418		
1473 759 FISH & NEAVE		EXAMINER SRIVASTAVA, KAILASH C			
ROPES & GRAY	LLP				
1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			. ART UNIT	PAPER NUMBER	
1,2,, 1,0,1,0,1,1		1657			
SHORTENED STATUTORY F	PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS 01/0		01/08/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

			No.	Applicant(s)					
Office Action Summary		10/717,275		CHEUNG, LING YUK					
		Examiner		Art Unit					
		Dr. Kailash C		1657					
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply								
WHIC - Externafter - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL' CHEVER IS LONGER, FROM THE MAILING Donsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period or the toreply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS 36(a). In no event, will apply and will exe, cause the applica	COMMUNICATION however, may a reply be tim spire SIX (6) MONTHS from the become ABANDONED	l. ely filed he mailing date of this O (35 U.S.C. § 133).					
Status	·		•		•				
1) 又	Responsive to communication(s) filed on 16 O	october 2006	•						
· 2a)□	•		-final						
3)	This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is								
٠٠/١	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Dispositi	ion of Claims								
4)⊠	Claim(s) <u>1-10</u> is/are pending in the application.								
•	4a) Of the above claim(s) <u>1-9</u> is/are withdrawn from consideration.								
	Claim(s) is/are allowed.								
6)⊠	Claim(s) 10 is/are rejected.								
	Claim(s) is/are objected to.				•				
8)	Claim(s)are subject to restriction and/o	r election requ	uirement.	The state of the s	Marian and an and an and and an and an and an and an and an an and an an and an and an and an and an and an an an and an an an and an an an and an				
Applicati	on Papers								
9)	The specification is objected to by the Examine	er.	•		•				
·	The drawing(s) filed on is/are: a) acc		objected to by the E	xaminer.					
	Applicant may not request that any objection to the		•	·					
	Replacement drawing sheet(s) including the correct				CFR 1.121(d).				
11)	The oath or declaration is objected to by the Ex	kaminer. Note	the attached Office	Action or form F	PTO-152.				
Priority u	ınder 35 U.S.C. § 119			•					
12)[7]	Acknowledgment is made of a claim for foreign	priority unde	: 35 U.S.C. & 119(a)	(d) or (f)	•				
_	☐ All b)☐ Some * c)☐ None of:	, p. 1. 2. 1. 2	3 (2)	(4) 6. (.).					
- /-	1. Certified copies of the priority documents	s have been r	eceived.						
	2. Certified copies of the priority documents have been received in Application No								
•	3. Copies of the certified copies of the prior				l Stage				
	application from the International Bureau								
* S	See the attached detailed Office action for a list	. •	` ''	d.					
	·				•				
Attachmen			-						
1) Motice of References Cited (PTO-892) 4) Interview Summary (PTO-413) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date									
3) 🔯 Information Disclosure Statement(s) (PTO/SB/08) 5) 🔲 Notice of Informal Patent Application									
Pape	r No(s)/Mail Date <u>3/7,3/24&4/11/05</u> .	6)	☐ Other:						

DETAILED ACTION

- 1. Applicant's amendment and response filed 16 October 2006 to Election requirement in Office Action mailed 14 June 2006 is acknowledged and entered.
- 2. The Art Unit Location for your application under prosecution at the United States Patent and Trademark Office (i.e., USPTO) has been changed to Art Unit 1657. To aid in correlating any papers for this application (i.e., 10/717,275), all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

Claims Status

- 3. Claim 11 has been cancelled.
- 4. Claims 1-9 have been withdrawn
- 5. Claim 10 has been amended
- 6. Claims 1-10 are pending.

Restriction/Election

- 7. Applicant's election without traverse of Group IV, Claim 10 in the response filed 16 October 2006 is acknowledged and entered.
- 8. Claim 10 is examined on merits

Information Disclosure Statement

9. Applicant's Information Disclosure Statements (i.e., IDS) filed 23 April 2004, and 7 March, 24 March and 11 April 2005 are acknowledged, made of record and have been considered.

Applicant's Information Disclosure filed 23 April 2004 is not on a PTO1449. In response to this Office Action, Applicant needs to file a proper PTO 1449 listing on said PTO1449 all the references cited in the Information Disclosure filed 23 April 2004.

Objection To Title

10. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed, which is a method to prepare compositions comprising yeast treated with electromagnetic energy. Examiner suggests the following title for the instant invention. "A Method To Prepare a Composition Comprising Culturing Yeasts in Presence of Alternating Electric Current".

Double Patenting

11. The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claim 10 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 12-13 of each of U.S. Patent Numbers 6,984,507; 6,984,508; 6,987,012 and 6,989,253 Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of an electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 9 of the instant application.

- 13. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 13 of co-pending Application Number 10/185,276 and Claims 13-17 of co-pending Application Number 10/184,749. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 9 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
- Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 30-36 and 43 of each of the following co-pending non-provisional United States Patent Application Numbers 10/460,246; 10/460,247; 10/460,271; 10/460,324; 10/460,325; 10/460,326; 10/460,328; 10/460,337; 10/460,338; 10/460,437; 10/460,438; and 10/460,530; 10460,832 and 10/460,833. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of *Saccharomyces cerevisiae* in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 10 of the instant application. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.
- 15. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 10 of Co-pending U.S. Non-Provisional Application Number 10/717, 008 and Claim 9 of Co-pending U.S. Non-Provisional Application Number 10/717, 134. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method comprising culturing a plurality of yeast cells of Saccharomyces cerevisiae in presence of electric field of certain frequency expressed in MHz and at certain field strength expressed in mV/cm to prepare a yeast composition is a substantially similar process to one that is Claimed in Claim 10 of the instant application. This is a provisional

obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 112

16. The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claim 10 is rejected under 35 U.S.C.§ 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since a specific strain of a microorganism, i.e., Saccharomyces cerevisiae Hansen AS2.560 is recited in the claims, said Saccharomyces cerevisiae Hansen AS2.560 is essential to the invention recited in those claims. Therefore, the Saccharomyces cerevisiae Hansen AS2.560 obtained after treating a yeast with a plurality of electromagnetic fields should be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, a deposit of the microorganism may satisfy the requirements of 35 U.S.C. §112.

It is noted that applicants have deposited the *Saccharomyces cerevisiae* Hansen AS2.560 *but* there is no indication in the specification as to public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide

assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

- a. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- b. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- c. the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- d. the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807, which states:

- (b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
 - i. The name and address of the depository;
 - ii. The name and address of the depositor;
 - iii. The date of deposit;
 - iv. The identity of the deposit and the accession number given by the depository;
 - v. The date of the viability test;
 - vi. The procedures used to obtain a sample if the test is not done by the depository; and
 - vii. A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
 - i. The accession number for the deposit;
 - ii. The date of the deposit.

35 U.S.C. § 112, Second Paragraph

18. Following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

- 19. Claim 10 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - From the currently presented claim language in Claim 10, it is not clear whether Saccharomyces cerevisiae Hansen AS2.560 is the yeast strain obtained after culturing commercially available plurality of Saccharomyces cerevisiae yeast cells to the claimed alternating electric field of a plurality of particular frequency and field strength for a given amount of time, or it is the Saccharomyces cerevisiae Hansen AS2.560 that is cultivated in alternating electric field of a plurality of particular frequency and field strength for a given amount of time. Appropriate clarification is required.

Claim Rejections - 35 U.S.C. § 103

20. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claim 10 is rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Zhang (U.S. Patent 5.578,486) in view of Zhang et al (Bioelectrochemistry and Bioenergetics, 28:341-358, 1992).

Claim recites a method to prepare a biological composition by culturing *Saccharomyces* cerevisiae yeast cells in presence of an alternating electric field of a plurality of particular frequency and field strength for a given amount of time.

Zhang (U.S. Patent 5,578,486, i.e., Zhang'486) teaches a method to treat *Saccharomyces* yeasts to a plurality of electromagnetic field (i.e., EMF) of varying amplitudes and frequencies for making a biological composition (Column 6, Lines 14-15). Zhang'486 does not teach the duration of culturing said yeasts in said plurality of electromagnetic fields. Zhang et al (Bioelectrochemistry and Bioenergetics, 1992) teach culturing *Saccharomyces* yeasts under careful control of temperature, pH and glucose concentration (Figure 1;Page 345, Lines 11-18; Lines 23-31; Lines 35-43 and Page 347, Lines 1-2 below Figure 4) with EMF.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Zhang with those from Zhang et al. to obtain a method to culture yeasts with a plurality of electromagnetic fields of varying amplitude and frequency to create yeast strains cultured in presence of electromagnetic force, wherein said yeasts are *Saccharomyces* yeast, because individual and combined teachings from each one of Zhang and Zhang et al. teach a method to culture yeasts in presence of a plurality of electromagnetic fields of varying amplitude and frequency, wherein said yeasts are *Saccharomyces cerevisiae*.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Zhang'486 according to the teachings from Zhang et al. to obtain a method to cultivate yeasts with a plurality of electromagnetic fields of varying amplitude and frequency, wherein said yeasts are *Saccharomyces* yeast, because Zhang and Zhang et al. teach the methods to cultivate *Saccharomyces* yeast applying same components and steps as instantly claimed and Zhang further teaches to make a biological composition applying said method to treat yeast with a plurality of electromagnetic fields of different amplitudes and frequencies. The prior art references do not teach the same exact *Saccharomyces cerevisiae* strain or amplitudes and frequencies of electromagnetic fields as instantly claimed. However, the adjustment of particular conventional working conditions (e.g., concentration of a particular

component in a given method, range of temperature, pressure, and other experimental parameters that are interchanged for the same effect) is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

- 22. For reasons aforementioned, no Claims are allowed.
- 23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava, Ph.D.

Patent Examiner Art Unit 1657

(571) 272-0923

December 20, 2006

DAVID M. NAFF PRIMARY EXAMINER ART UNIT 128 / Y